UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,656	06/20/2003	Bill E. Cham	13131-0310 (44378-282108)	8075

23370 7590 09/22/2004

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,656	CHAM ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 20 June 2003.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. In a telephone interview with Applicant's representative, John McDonald, on September 13, 2004, a new restriction requirement was requested in view of the improper lack of unity standard that was applied to the pending claims in the Restriction requirement of August 12, 2004. In response, the previous restriction requirement is withdrawn. In its place is the following new restriction requirement.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claim 1 link(s) inventions I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

I. Claim 2, drawn to a modified immunodeficiency virus particle, classified in class 424, subclass 207.1.

II. Claim 2, drawn to a modified hepatitis virus particle, classified in class 424, subclass 225.1.

III. Claim 2, drawn to a modified pestivirus particle, classified in class 424, subclass 218.1.

- Claims 3-5, 18, 19 and 22-27 link(s) inventions IV-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s) 3-5, 18, 19 and 22-27.

IV. Claims 3-5, 18, 19 and 22-27 drawn to a method of making a modified immunodeficiency virus particle, classified in class 435, subclass 235.1.

V. Claims 3-5, 18, 19 and 22-27 drawn to a method of making a modified hepatitis virus particle, classified in class 435, subclass 235.1.

VI. Claims 3-5, 18, 19 and 22-27 drawn to a method of making a modified pestivirus particle, classified in class 435, subclass 235.1.

VII. Claims 6-8, drawn to an antigen delivery vehicle comprising patient specific antigens, classified in class 424, subclass 184.1.

VIII. Claims 9 and 10, drawn to a method of providing protection against an infectious viral particle, classified in class 435, subclass 5.

IX. Claims 11-17 and 20-27, drawn to a method of provoking an immune response using patient specific antigens, classified in class 435, subclass 5.

3. The inventions are distinct, each from the other because of the following reasons:

a) Groups I-III are drawn to different viral particle compositions comprising immunodeficiency virus, hepatitis virus and pestivirus particles. A search for an immunodeficiency virus is not co-extensive for hepatitis and pestivirus. These viruses have different structures, genomic content, modes of operation, function and effect. For similar reasons, Groups IV-VI are distinct because methods of producing viruses differ from virus to virus. In the instant case, methods of producing HIV, Hepatitis and pestivirus require different reagents and method steps.

b) Groups (I-III) and (IV-VI) are related as process of making and product made, respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products can be made by a materially different process, such as treatment with a detergent.

c) Groups (I-III) and VII are drawn to different compositions. The compositions of Groups I-III contain viral particles. The composition of Group VII contains patient specific antigens. A search for the viral particles of Groups I-III is not co-extensive with a search for patient specific antigens.

d) Inventions (I-III) and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a diagnostic assay.

e) Inventions (I-III) and IX are unrelated. The products of Groups I-III are not required for the method of providing protection using patient-specific delipidated viral particles.

f) Inventions (IV, V, VI), VIII and IX are all unrelated. The methods of Groups IV-VI are drawn to the delipidation of different types of viral particles. The method of Group VIII is drawn to providing protection against infectious viral particles. The methods of Groups IV-VI (collectively) and Group VIII do not share modes of operation, function or effect. They are not disclosed as capable of use together. The methods of Groups IX and X are drawn to providing protection using patient specific delipidated viral particles, not required for the practice of any other method or disclosed as capable of use with other methods.

g) Inventions (IV-VI) and VII are unrelated. The methods of Groups IV-VI do not require the patient-specific antigen delivery vehicle of Group VII.

h) Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a diagnostic assay.

i) Inventions VII and IX are related as product and process of use. The product of Group VII can be used in a diagnostic assay.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because these inventions are distinct for the reasons given above and the literature

search required for one group is not co-extensive for any other group, restriction for examination purposes as indicated is proper. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product

and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SBC

Stacy B. Chen
September 13, 2004

James C. Housel 9/20/04
JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600